

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/780,060	KITSON ET AL.	
	Examiner Marina Lamm	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS**. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Board Decision.
2.  The allowed claim(s) is/are 4,5 and 10-13.
3.  The drawings filed on 09 February 2001 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
 of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

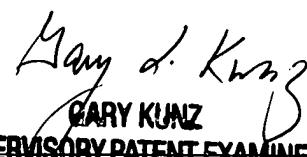
\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.



GARY KUNZ

SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Please cancel Claims 1-3, 6-9, 14-19 and 22-40.

Please substitute Claims 4, 5, 10, 11 and 13 with amended Claims 4, 5, 10, 11 and 13 as follows:

Claim 4 (amended): A skin barrier replacement composition comprising an aqueous formulation of at least three lipids in a non-crystalline phase lamellar array which adopt a crystalline lamellar phase upon application to mammalian skin, wherein the at least three lipids comprise a ceramide, a saturated fatty acid and cholesterol and wherein the composition comprises bovine brain ceramide as the ceramide, palmitic acid as the saturated fatty acid and cholesterol in ratios by mol of from 1-5:1-5:1-5, respectively.

Claim 5 (amended): A skin barrier replacement composition comprising an aqueous formulation of at least three lipids in a non-crystalline phase lamellar array which adopt a crystalline lamellar phase upon application to mammalian skin, wherein the at least three lipids comprise a ceramide, a saturated fatty acid and cholesterol and

wherein the composition comprises ceramide 2 as the ceramide, palmitic acid as the saturated fatty acid and cholesterol in ratios by mol of from 1-5:1-5:1-5, respectively.

Claim 10 (amended): A skin barrier replacement composition comprising an aqueous formulation of at least three lipids in a non-crystalline phase lamellar array which adopt a crystalline lamellar phase upon application to mammalian skin, wherein said non-crystalline phase is a gel.

Claim 11 (amended): A skin barrier replacement composition comprising an aqueous formulation of at least three lipids in a non-crystalline phase lamellar array which adopt a crystalline lamellar phase upon application to mammalian skin, wherein said non-crystalline phase is a complex phase.

Claim 13 (amended): A skin barrier replacement composition comprising an aqueous formulation of at least three lipids in a non-crystalline phase lamellar array which adopt a crystalline lamellar phase upon application to mammalian skin, wherein said crystalline phase induced upon application to the skin is greater than 70% crystalline as measured by deuterated fatty acid mobility in NMR.

***Allowable Subject Matter***

2. Claims 4, 5 and 10-13 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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7/24/04